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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/689,508	10/12/2000	Scott A. Ruddell	DI-5654	9098

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EXAMINER	
LAM, ANN Y	
ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 02/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/689,508	RUDDELL ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-37 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-37 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1 and 3-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Zakko, 5,527,274. Zakko discloses a tube (see Figure 4) having an implantable portion (i.e., distal portion of tube) extending from an external patient portion (i.e., proximal portion of tube), the implantable portion having a curved segment between the external patient portion and a distal end of the implantable portion; a first lumen (54) extending through the tube from a first lumen port in the external patient portion (i.e., infusion port in the proximal end of tube) to a first lumen port (60) in the curved segment of the implantable portion; and a second lumen (50) extending through the tube from a second lumen port in the external patient portion (i.e., aspiration port in the proximal end of tube) to a second lumen port (62) in the implantable portion, the second lumen port in the implantable portion being spaced away from the first lumen port in the curved segment, see also column 17, lines 43-50.

As to claim 3, the first lumen port in the curved segment comprises a plurality of openings (60) at an outer radial surface of the curved segment.

As to claims 4, 7, 10, the plurality of openings are substantially round holes, see Figure 5.

As to claims 5, 8, 11, the plurality of openings are considered slots, see Figure 5.

As to claim 6, the implantable portion has a coiled shape at the distal end, see Figure 4.

As to claim 9, the implantable portion has a substantially straight shape at the distal end, see Figure 5.

As to claim 12, the tube is a single tube having a septum between the first and second lumens, see Figure 3.

As to claim 13, the first lumen port (60) in the curved segment is a patient inflow port, see column 17, lines 45-47.

As to claim 14, the second lumen port (62) in the implantable portion is a patient outflow port, see column 17, lines 48-50.

As to claim 15, the first lumen (54) terminates prior to the distal end of the implantable portion, see column 17, lines 33-34, and column 18, lines 1-2.

As to claim 16, Zakko discloses a connection section having an inflow port (one of the proximal ports in Figure 4) to a patient inflow lumen, and an outflow port (one of the proximal ports in Figure 4) to a patient outflow lumen; a patient inflow section extending from the connection section and having a patient inflow opening (60) to the patient inflow lumen; a separation section extending from the patient inflow section; and a patient outflow section extending from the separation section and having a patient outflow opening (62) to the patient outflow lumen.

As to claim 17, when the catheter is in a substantially unstressed condition, the connection section is substantially straight, the patient inflow section is curved, and the separation section is substantially straight.

As to claim 18, the patient outflow section is coiled.

As to claim 19, the patient outflow section is substantially straight.

As to claim 20, the patient inflow section is considered an uppermost portion of an implantable portion of the catheter and the patient outflow section is considered a lowermost portion of the implantable portion of the catheter.

As to claim 21, the connection section, patient inflow section, separation section, and patient outflow section further comprise a flexible tube having an internal septum between the patient inflow and outflow lumens, see Figure 3.

As to claim 22, the patient inflow section has a curved shape, see Figure 5.

As to claim 23, the patient inflow opening to the patient inflow lumen is in a direction away from the patient outflow opening to the patient outflow lumen.

As to claim 24, the catheter comprises a single tube having the patient inflow (54) and outflow (50) lumens, and wherein the tube transitions from having both the patient inflow and outflow lumens to having only the patient outflow lumen (50) at a location between the patient inflow section and a distal catheter end.

As to claim 25, Zakko discloses a flexible single tube having first and second lumens, the first lumen (54) extending from a first fluid opening (one of the proximal openings in Figure 4) to a second fluid opening (60), the second lumen (50) extending from a third fluid (one of the proximal openings in Figure 4) opening to a fourth fluid

opening (62), the first and third fluid openings being in an external patient portion of the catheter (i.e., proximal portion of the catheter), the second and fourth fluid openings being in an implantable portion of the catheter (i.e., distal portion of the catheter) and spaced apart from each other, the implantable portion of the catheter have a generally non-linear shape, see Figure 5.

As to claim 26, the second fluid opening is located at a non-linear shaped section of the implantable portion, see Figure 5.

As to claim 27, the second (60) and fourth (62) fluid openings are separated by a substantially linear tube section which is absent fluid openings to an exterior of the catheter, see Figure 5.

As to claim 28, the second fluid opening (60) is located at a vertically uppermost portion of the implantable portion and the fourth fluid opening (50 and 62) is located at a vertically lowermost portion of the implantable portion, see column 18, lines 1-2.

As to claim 29, Zakko discloses a substantially straight connection section (i.e., proximal portion of catheter); a non-linear patient inflow section extending from the connection section (i.e., portion of catheter near 60); a separation section extending from the patient inflow section (i.e., portion of catheter in between 60 and 62); a patient outflow section (i.e., portion of catheter near 62) extending from the separation section; a patient inflow lumen (54) extending from the connection section to the patient inflow section; and a patient outflow lumen (50) extending from the connection section to the patient outflow section.

As to claim 30, the separation section has a substantially straight shape, see Figure 5.

As to claim 31, the patient outflow section has a coiled shape, see Figure 4 or 5.

As to claim 32, the patient inflow section has a curved shape of about 180 degrees. The catheter is capable of having a shape of about 180 degrees, see column 4, lines 37-38, and thus the catheter is considered to have a curved shape of about 180 degrees, as claimed by Applicant.

As to claim 33, Zakko discloses a dialysis machine connection section (i.e., proximal section of catheter) having fluid ports to first and second lumens; a non-linear section (i.e., section of catheter near 60 in Figure 4) extending from the connection section and having a fluid port to the first lumen; a separation section (i.e., section of catheter in between 60 and 62) extending from the non-linear section; and a distal end section (i.e., section of catheter near 62) extending from the separation section and having a fluid port to the second lumen.

As to claim 34, the first lumen is a patient inflow lumen and the second lumen is a patient outflow lumen, see column 17, lines 43-50.

As to claim 35, the non-linear section has a curved shape and the fluid port in the non-linear section is considered pointed in a direction opposite the fluid port in the distal end section, see Figure 4.

As to claim 36, Zakko discloses a method comprising the steps of: flowing fluid into a first lumen at a proximal end of the catheter; flowing the fluid in the first lumen to a curved path of the first lumen; flowing the fluid in the curved path through a fluid

opening in the curved path and out of the catheter; flowing the fluid which exited the catheter from the opening in the curved path into a second lumen at a distal end of the catheter; and flowing the fluid in the second lumen to a fluid opening at the proximal end of the catheter and out of the catheter, see column 17, lines 29 – column 18, line 8.

2. Claim 37 is rejected under 35 U.S.C. 102(b) as being anticipated by Moncrief et al., 5,057,075.

Moncrief et al. discloses the steps of straightening the catheter with a stylet inside the catheter see column 5, lines 4-5; inserting a distal end of the straightened catheter through an entrance incision into a peritoneal cavity of the patient while directing the straightened catheter downward, see column 4, lines 58-68; removing part of the stylet from the catheter while advancing the catheter into the peritoneal cavity until the distal end is located in a lower area of the peritoneal cavity and a distal implant cuff is seated in a rectus muscle of the patient; rotating a portion of the stylet and catheter outside of the patient downward and a portion of the stylet and catheter inside of the patient upward, see column 5, lines 7-17; and pulling the catheter through a subcutaneous tunnel having an exit site below the entrance incision, see column 6, lines 22-32.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Zakko, 5,527,274, in view of Moncrief et al., 5,057,075.

Zakko discloses the invention substantially as claimed, see above. However, Zakko does not disclose an implant cuff.

Moncrief et al. discloses a catheter for implantation having a cuff (24) that is amenable to in-growth of living tissue, see column 2, lines 19-25. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide an implant cuff on the Zakko device for implanting the catheter into a living body, as taught by Moncrief et al.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Martin, 5,188,593, and Sommercorn et al., 4,543,087, both disclose a dual lumen catheter with openings.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on T-F 8-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703)308-3552. The fax phone numbers for

the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703)306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

A.L.
February 10, 2002

Brian L. Casler
Primary Examiner